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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,874	12/15/2005	Toshiya Kai	IWT-001	6777
20374 7590 11/25/2008 KUBOVCIK & KUBOVCIK SUITE 1105 1215 SOUTH CLARK STREET ARLINGTON, VA 22202				
EXAMINER				
KISHORE, GOLLAMUDI S				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
11/25/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/534,874

Applicant(s)

KAI ET AL.

Examiner

Gollamudi S. Kishore, Ph.D

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The RCE dated 7-2-08 is acknowledged.

Claims included in the prosecution are 1-13.

In view of the amendments, the 112, first paragraph rejection is withdrawn.

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 1 recites 'wild-type human serum albumin'. There is no specific definition for the term in the specification; is it the applicant's intent to convey 'naturally occurring human serum albumin'?

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2, 5-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Kamps (BBA, 1996) of record.

Kamps discloses liposomes, which have both albumin and PEG, are bonded

(abstract, Materials and Methods). Instant claim 2 simply recites a physiologically active substance and therefore, the reference, which teaches the internalized buffer, meets the requirements of instant claim.

Applicant's introduction of 'wild-type human serum albumin is noted. There is no definition of this term in the specification and therefore, the term is interpreted as 'naturally occurring albumin'.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tardi (J. Immunological methods, 1997) by itself or in combination with Jacobson (US 2002/0132328) or Mayo (US 2002/0146406)

Tardi discloses liposomes which have both ovalbumin and PEG on their surfaces and such liposomes are immunogenic. The liposomes further contain doxorubicin. Ovalbumin is modified with the amine reactive cross linker SPDP according to the procedures of Loughery (using N- (3-(2-pyridyldithio) propionyl) phosphatidylethanolamine), which is cited of interest (abstract, Materials and Methods, Figure 1). Tardi however, does not teach the binding of serum albumin. The use of

serum albumin instead of ovalbumin would have been obvious to one of ordinary skill in the art since a similar binding occurs. One of ordinary skill in the art would be motivated to use serum albumin instead of ovalbumin because of the equivalency between ovalbumin and human serum albumin taught by Jacobson (0123) or Mayo (0059).

8. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zalipski (6,180,134) in view of Kamps (BBA, 1996) optionally in combination with Jacobson or Mayo cited above or vice versa (Kamps and optionally either Jacobson or Mayo in view of Zalipski).

Zalipsky while disclosing liposomal formulations wherein the liposomal surface is attached to both PEG and protein teaches that the protein coupled to PE-PEG maleimide was much higher than either the MPB maleimides (Fig. 9; col. 11, line 62 through col. 13, line 10).

Kamps discloses liposomes, which have both albumin and PEG, are bonded (abstract, Materials and Methods).

Jacobson and Mayo each teach the equivalency between ovalbumin and human serum albumin.

The attachment of serum albumin taught by Kamps as the protein in Zalipsky would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since albumin is a protein and one would expect similar attachment. Alternately to attach albumin to PEG-PE of the liposomes of Kamps would have been obvious to one of ordinary skill in the art since more albumin can be attached as taught by Zalipsky and because more protein can be attached as taught by Zalipsky. The use

of human serum albumin instead of ovalbumin would have been obvious to one of ordinary skill in the art because of the equivalency taught by Jacobson and Mayo.

Applicant's arguments have been fully considered, but are deemed to be moot in view of the new rejections.

The references of Gillies (US 2003/0166877) and Carter (5,585,466) which teach wild-type albumins are cited as interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612

GSK